

REMARKS

Claims 1-8 and 10-19 are currently pending in the application. Aside from the corrected markings of the previous Amendment, no claims have been amended and no new claims have been added.

Information Disclosure Statement

The Applicant gratefully acknowledges the Examiner and his supervisor's willingness to discuss the appropriate format for Information Disclosure Statement submissions. The Applicant now submits the enclosed Eighth Supplemental Information Disclosure Statement in accordance with these discussions.

Updated Notice of Related Litigation

Applicant has submitted four Notices of Related Litigation to keep the Office apprised of the events and substantive papers filed in a litigation involving two patents issuing from continuation applications that claim priority to the patent involved in the instant reissue application. As seen by the Joint Stipulation of Dismissal filed February 14, 2005, the parties have now settled the litigation. Applicant now encloses a Fifth Updated Notice of Related Litigation and respectfully requests the Office to consider the attached court documents.

Oath/Declaration

The Examiner provides several comments regarding the reissue oath/declaration, which Applicant addresses below.

First, the Examiner states a supplemental oath or declaration is required under 37 C.F.R. § 1.67 because the application claims new subject matter not originally claimed or embraced in the statement of the invention. Office Action at 3. Accordingly, Applicant hereby submits with

this paper a supplemental reissue declaration signed by the inventor, Dr. Graham E. Kelly that specifies at paragraph 8 in accordance with MPEP § 1414.01 at 1400-37 that:

All the errors that are being corrected in the present reissue application up to the time of the filing of this supplemental oath/declaration, and that are not covered by a prior oath/declaration submitted in this application, arose without any deceptive intent on the part of the Patent Owner and of the inventor.

In addition, the Examiner rejected claims 1-8 and 10-19, alleging the original reissue oath/declaration is defective because it fails to identify at least one error that is relied upon to support the reissue declaration. Office Action at 3. The Examiner asserts that “any error in the claims must be identified by reference to the specific claims and the specific claim language wherein lies the error.” *Id.* Applicant respectfully disagrees because the original oath/declaration did provide this precise information. Specifically, as set forth below, paragraphs 6-8 of the original oath/declaration expressly identified (1) the claims that were in error (claims 11-13), (2) the specific language in the claims that led to the error, (3) the inventor’s belief that “the invention could be more broadly expressed,” and (4) the specific language that would correct the error:

6. I believe that U.S. Patent No. 5,830,887 is partially inoperative by reason of my having claimed less than I had a right to claim.

7. An error which is the statutory basis for reissue is that the patent fails to contain claims of appropriate scope. Claims 11-13 are currently directed to:

[A] pharmaceutical preparation, in solid dosage unit form, the biological active component of said preparation **consisting essentially of** any two or more concentrated, phytoestrogen-derived isoflavones selected from the group consisting of Genistein, Daidzein, Biochanin A, Formononetin or the natural glycosides of any said

phytoestrogens and said preparation including a
pharmaceutically acceptable carrier.

At the time I filed the patent application, I did not appreciate that
invention could be more broadly expressed as:

[A] pharmaceutical preparation, in solid dosage unit form,
the biological active component of said preparation
comprising any two or more concentrated, phytoestrogen-
derived isoflavones selected from the group consisting of
Genistein, Daidzein, Biochanin A, Formononetin or the
natural glycosides of any said phytoestrogens and said
preparation including a pharmaceutically acceptable carrier.

Nevertheless, I consider such a broad expression to be part of my
invention, and I seek broadened claims in the present reissue application.

8. All errors being corrected in the reissue application up to the time
of filing the present Declaration arose without any deceptive intention on
my part.

Thus, contrary to the Examiner's assertions, Dr. Kelly does more than merely show the
error through reproducing the claims. Because Dr. Kelly has clearly provided a sufficient
original oath/declaration, Applicant respectfully requests the withdrawal of the defective reissue
rejection of claims 1-8 and 10-19.

Response to Amendment

The Examiner also requires a supplemental paper correcting the format of the amended
claims in the Amendment filed on September 19, 2003, because the amended claims do not
comply with 37 C.F.R. § 1.173(b) and (d). Office Action at 4. According to 37 C.F.R. §
1.173(d), "(1) The matter to be omitted by reissue must be enclosed in brackets; and (2) The
matter to be added by reissue must be underlined." The markings showing the changes to the
claims have been amended in compliance with § 1.173(d). The substance of the claims remains
the same and no new amendments have been made. Accordingly, Applicant respectfully
requests the consideration and timely allowance of the pending claims.

Conclusion

Again, the Applicant's representative would like to thank Examiner Lewis and Supervisor Wilson for their willingness to address these disclosure formalities as expeditiously as possible. If any issues remain unresolved, the Examiner is invited to call the Applicant's representative at 650-849-6607.

If there is any fee due in connection with the filing of this Response, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: August 5, 2005

By: Jean B. Fordis
Jean B. Fordis
Reg. No. 32,984